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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,542	07/27/1999	DOUGLAS JOSEPH DOBROZSI	7247M	5652

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
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CINCINNATI, OH 45202

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/361,542	DOBROZSI, DOUGLAS JOSEPH	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,38,41-43,46 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,38,41-43,46 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of remarks dated 6-5-08 is acknowledged.

Claims 36, 38, 41-43, 46 and 48 are pending in the application.

Response to Arguments

1. Applicant's arguments, see pages 2-6, filed 6-5-08, with respect to the rejection(s) of claim(s) 36, 38, 41-43, 46 and 48 under 35 USC 103(a) as being unpatentable over US 5,112,604 ('604) in view of US 4,680,312 ('312) and Remington's Pharmaceutical sciences, 18th edition (page 340) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 36, 38, 41-43, 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,682,747 to Turck et al ('747) as evidenced by Univar (Product sheet) or unpatentable over US 5,112,604 ('604) in view of '747 patent to Turck as evidenced by Univar (Product sheet).

4. Turck teaches a process for preparing oral liquid preparation of a pharmaceutical substance comprising a pharmaceutically active such as an NSAID, stabilized by the addition of a highly dispersed silicon dioxide (abstract, col. 1, L 55-59 and lines bridging col. 2-3). The specific surface area of silicon dioxide is given col. 3, L 25-29 and the amount of silicon dioxide ranges from 0.1% to 5% by weight (col. 4, L 13-

16) and for the active agent see col. 4, L 24-28. In particular, Turck states surface area in the range of 100-400 mg^2/g and mentions AEROSIL 200. While Turck fails to teach the particle size of highly dispersed colloidal silicon dioxide, the product sheet of Univar (Product sheet) shows that the surface area of colloidal silicon dioxide particles in the range of 100 or 90 mg^2/g has particles in nanometer size range. Thus, the amount of silicon dioxide and its particle size taught by Turck are within the claimed percentages of silicon dioxide. For the claimed active agents, Turck teaches NSAIDs that meet the claimed analgesics and also antirheumatoid agents (col. 6, L 34-35). Turck also teaches that NSAID, meloxicam, exhibits pH-dependent solubility and requires an aqueous buffer system (col. 5, L 60-67) and suggests an aqueous buffer system as a suitable dispersion medium for the liquid oral suspension (col. 6, L 4-8; L 56-64). With respect to the preparation of the composition, Turck teaches (example in col. 9) including citric acid monohydrate in the buffering system. While Turck fails to teach the amount of citric acid and water in the claimed amounts, it would have been obvious for one of an ordinary skill in the art at time of the instant invention was made to employ suitable amounts of the above two components with an expectation to obtain an optimal aqueous buffer system so as to achieve the desired solubility of the drug because Turck teaches aqueous buffer system for solubilizing NSAID. The limitation that the mixture forms a gel-like mixture upon contact with a mucosal surface is an intended use and further, Turck teaches all of the claimed components and therefore the burden is shifted to applicants to show that the gel formation does not occur with the composition of Turck.

Alternatively,'604 teaches oral, aqueous suspension formulations comprising a drug, a wetting agent, a hydrocolloid gum, colloidal silicon dioxide, antifoaming agent, citric acid, water and other components (col. 1, lines 40-57 and tables 1 and 2). With respect to the drug, '604 teach addition of anti-tussive, anti-inflammatory, bronchodilator etc (col. 3, lines 47- 56), similar to those claimed in the instant. '604 teach the same amount of citric acid that falls within the instant claimed range (tables). With respect to the size of colloidal silicon particles, while '604 do not mention the particle size, the reference teaches "colloidal" silicon dioxide which by definition has a particle size in the range of nanometers (admitted on page 4, lines 29-36 of instant specification). However, '604 also desired colloidal silica and teach Aerosil 200 and according to the product description of Univar (Product sheet), the particle size is in the nanometer range. '604 teach oral suspension that read on the claimed method of administering a medicament by swallowing the composition. '604 fail to specify the amount of water in the composition. However, both the examples of '604 recite ingredients that include water in the simple syrup preparation (col. 6, lines 14-20 and claim 1). Accordingly, absent unexpected advantage with the claimed high amounts of water, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include the appropriate amount of water to prepare an oral aqueous liquid composition of desired viscosity. '604 teach up to 2% silicon dioxide and not 3% -20% (claim 36 and 42) or 3% to 15% (claims 38).

5. Turck, discussed above, an oral liquid preparation of a pharmaceutical substance comprising a pharmaceutically active such as an NSAID, stabilized by the addition of a

highly dispersed silicon dioxide (abstract, col. 1, L 55-59 and lines bridging col. 2-3). The specific surface area of silicon dioxide is given col. 3, L 25-29 and the amount of silicon dioxide ranges from 0.1% to 5% by weight (col. 4, L 13-16) and for the active agent see col. 4, L 24-28. Thus, the amount of silicon dioxide taught by Turck overlaps with the claimed percentages of silicon dioxide. Turck teaches that the addition of a highly dispersed colloidal silicon dioxide in the disclosed amounts stabilizes the composition without increasing the viscosity and retains the ability to reconstitute without causing a gel like substance (col. 3, L 1-27 and col. 8, L 58-67). Thus, both Turck and '604 desire a stable oral aqueous suspension without too much viscosity and Turck teaches that small amounts of silicon dioxide (colloidal) achieves the same. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include colloidal silicon dioxide in amount ranging between 0.1-5% by weight of the composition with an expectation to stabilize the composition without forming a gel like substance.

> Applicants argue – "in the specification at page 7, beginning at line 10, the term "gel" describes the substance resulting from the combination of mucin/saliva mixture and the formulation of the present invention. Beaurline does not disclose, suggest or provide motivation or expectation of success for a composition that would form a gel-like mixture upon contact with a mucosal surface as recited in the present Claims. The objective of Beaurline is to create a stable suspension, not to create a gel-like mixture upon contact with a mucosal surface and thus Beaurline provides no motivation for, or expectation of success in, creating a

liquid aqueous mucoretentive composition that forms a gel-like mixture upon contact with a mucosal surface." While it is noted that neither of the patents (Turck or '604) patents teach the ability to form gel, the property is an intended use and further the compositions disclosed by the patents render the instant claims obvious and hence the ability to form a gel upon contact with mucosal surface. This is further substantiated by applicants' own statement that the term "gel" describes the substance resulting from the combination of mucin/saliva mixture and the present formulation. Because the composition of Turck or Turck and '604 renders the instant formulation obvious, the resulting formulation from the above teachings does result in a gel upon interacting with mucin/saliva.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
Art Unit 1611
September 13, 2008